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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,098	06/24/2004	Anne D. Frame	94756/5	7662
7590 03/25/2008 Michael David Fried Frank Harris Shriver & Jacobson 1001 Pennsylvania Avenue NW Washington, DC 20004			EXAMINER LEITH, PATRICIA A	
			ART UNIT 1655	PAPER NUMBER
			MAIL DATE 03/25/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/500,098

Applicant(s)

FRAME, ANNE D.

Examiner

Patricia Leith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15, 26-35 and 39-49 is/are pending in the application.
- 4a) Of the above claim(s) 1-15, 26-31, 34, 35 and 42-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 32, 33 and 39-41 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/888)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION

The Finality of the previous Office action is hereby WITHDRAWN. The amendment filed on 10/26/07 after final Office action is hereby entered in order to present the following action.

Claims 1-15, 26-35 and 39-49 are pending in the application.

Claims 1-15, 26-31, 34-35 and 42-49 remain withdrawn from the merits as being directed toward a non-elected invention.

Claims 32-33 and 39-41 were examined on their merits.

In a series of telephone discussions with Attorney Michael David, a decision was reached to remove the previous rejection under 35 USC 112 first paragraph. Upon further review of the claims in light of the prior art references submitted by Applicant on 10/26/07, it is decided that the term 'organic solvent' reasonably meets the 112 first paragraph statute.

The following was also discussed with Attorney Michael David:

Upon further searching prior to allowance of the case, a reference was found which discloses an organic solvent extract of *Mammea americana*, however, does not disclose wherein the leaves in particular were extracted. While this reference suggests the use of other parts of *M. americana* can be used, the reference is not enabled for an antibacterial agent prepared by the method of the Instant claims. Further, there is no suggestion in the prior art reference that the extract from the leaves would produce the advantageous result of antimicrobial activity toward the specific microbes as demonstrated by the Instant specification, and further no suggestion to carry out a chromatography step on the crude extract.

However, during the same search and reconsideration of the claimed invention, a new reference was uncovered which is deemed to render obvious the claimed invention. A new rejection follows.

Mammea americana may be referred to herein as 'MA.'

Specification

The amendment filed 6/24/04 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: in the amendment to the

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specification filed on 6/24/04, Applicant has replaced all instances of 'cobaltocene-octomet' with 'cobaltocene-octomet.' Every instance of replacement of 'cobaltocene-octomet' with 'cobaltocene-octomet' is considered New Matter. It cannot be ascertained what compound 'cobaltocene-octomet' refers to, and thus, it cannot be absolutely ascertained if 'cobaltocene-octomet' is the equivalent of 'cobaltocene-octomet.'

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 32-33 and 39-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 32 recites 'wherein the plant material is from the leaves of *Mammea americana*...' (emphasis added). This statement is ambiguous and confusing because it cannot be ascertained if the plant material is the leaves of *Mammea americana*, or from

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a certain part of the leaf (i.e., the waxy layer of the leaf for example). Clarification is necessary.

Because claims 33 and 39-41 are either directly, or indirectly dependant upon claim 32, claims 33 and 39-41 necessarily possess all of the claim limitations of claim 32 and hence also contain ambiguous language and are also found indefinite for the same reasoning set forth for the rejection of claim 32 under this statute (*supra*).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 32-33 and 39-41 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Greenspan et al. (1996) in view of McMurry (1992).

Greenspan et al. (1996) disclosed a method for extracting leaves and seeds of *Mammea americana* to produce an insecticidal composition against larvae of *Diabrotica virgifera* v. (see entire reference). Specifically, Greenspan et al. lyophilized the seeds and leaves (respectively) and carried out individual hexane (organic solvent) extractions of the lyophilized seeds and leaves followed by thin layer chromatography to elucidate the compounds endogenous therein (see 'Materials and Methods', pp. 237-238).

Greenspan et al. did not explicitly teach wherein the extract was 'eluted', nor did they teach the particular constituents of the *Mammea americana* leaves as instantly claimed.

The use of chromatography in science is ubiquitous. Chromatography media are conventionally used to separate compounds in crude extract preparations based upon solubility, ionic charge and size for example (see McMurray pp. 413-414).

Although Greenspan et al. did not specifically teach elution of the extract from a chromatographic system, this is clearly because Greenspan et al. used TLC and not column chromatography to elucidate the MA extracts. One of ordinary skill in the art

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would have had a reasonable expectation of success in carrying out the claimed process in that the ordinary artisan would have been well-aware that column chromatography systems were well-known and well-utilized at the time the invention was made.

The only difference between the claimed invention and the invention of the prior art as taught by Greenspan et al. is that applicants eluted their extract from the column. There is no step in the method which indicates what type of column media was used (stationary phase), what fractions were collected, or what organic solvents were used. While the prior art did not specifically teach placing the crude MA extract over a column, but instead, chose to elucidate their extract via TLC, it is deemed that the ordinary artisan would have clearly recognized the advantage of using column chromatography for processing large batches of extract in order to manufacture and standardize the extract.

It is noted that wherein the claims state that the method is carried out in order to obtain an extract with antimicrobial activity is merely an intended use of the method. It is deemed that first, the ordinary artisan would have been motivated to use chromatography in order to characterize endogenous phytochemicals in the organic solvent extract of MA as keenly discussed above, in order to condense and purify active ingredients therein for manufacture and secondly, the ordinary artisan would have been motivated to perform this step even if it was for a different reason (to purify/isolate

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insecticidal compounds) than the reason Applicant gives in the claim (to obtain an antimicrobial extract). The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem; See MPEP § 2144:

It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. See, e.g., *In re Kahn*, 441 F.3d 977, 987, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006) (motivation question arises in the context of the general problem confronting the inventor rather than the specific problem solved by the invention) (emphasis added)

Further, because Greenspan et al. clearly taught an organic solvent extract of MA leaves, and the Instant specification teaches broadly that any organic solvent may be used to produce the claimed invention having the claimed characteristic phytochemicals, that the extract of Greenspan et al. also contained these phytochemicals absent sufficient evidence to the contrary. It is pointed out that claims which further limit the method to wherein particular phytochemicals are present do not specifically limit the method steps. Even though the intended use of the method does not materially change the steps in the method, it is noted that it is highly likely that the extract of Greenspan et al. was also antimicrobial in that it was a proven insecticide.

“As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith.” *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688

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(CCPA 1972). The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants' composition differs and, if so, to what extent, from that of discussed references. Therefore, with the showing of the references, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

The Supreme court has acknowledged that:

When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. **If a person of ordinary skill can implement a predictable variation..103 likely bars its patentability.**...if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond that person's skill. A court must ask whether the improvement is more than the predictable use of prior-art elements according to their established functions...

...the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results (see *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 U.S. 2007) emphasis added.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Primary Examiner
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/Patricia Leith/

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